

23R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities released in this Vault CDMS release that may affect a customer's vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. The RIA serves as an early preview of the Validation Impact Assessment (VIA). Once the VIA is available on Veeva Docs, refer to it for more detailed validation information.

This feature list is subject to change	e prior to the release. We will begin tracking changes on: 3/3/2023
Revision Date:	4/21/2023
VIA Available:	3/27/2023
For detailed feature descriptions, re	efer to the product release notes, which are available on Vault CDMS Help.
This document does not include ch	anges made as part of the Vault Platform release. Consult VeevaDocs for Vault Platform validation details.
Feature Risk:	Feature risk analysis takes into account data integrity, security, and confidentiality assuming the feature is turned on (either automatically or via configuration). Veeva performs validation testing on all High and Medium risk items.
High	May affect security, patient confidentiality, application areas that support GXP functions (audit trails, eSignature, etc.) or other ERES controls data
Medium	May affect core application functions (workflows, revision history, etc.)
Low	May affect metadata/notifications
N/A	The feature is a minor UI enhancement and not a functional change. The feature has no validation impact.
Enablement Fields:	These four fields describe the availability and visibility of a feature on day 1 (if no configuration occurs), what configuration is required, and if the feature has any dependencies.
Day 1 Impact to Primary Users	This feature is visible and available tone or more primary user teams (Site Users, Clinical Team, and Coders) on day 1. If blank, this feature is either only visible to study designers or administrator users, it requires configuration before it is visible to primary users.
Users with Day 1 Visibility	This feature is visible to these users on day 1 if no configuration occurs.
Configuration	This field lists the location(s) where configuration for this feature occurs, for example, "Studio" or "EDC Tools". "Support" indicates that this feature must be enabled by Veeva Support, and "Vault Admin" indicates that configuration must be performed by a Vault Owner in the vault's Admin area.
Dependencies	This field lists any dependencies required to use this feature, for example, Labs or Expression Engine V2. The RIA assumes that the dependencies are enabled.
Training Impact:	Lists the user roles that may require updated training for this feature.

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Site Users	"Complete" Button Renamed to "Submit"	EDC		Sites			Low	The <i>Complete</i> button on forms has been relabeled as <i>Submit</i> . Users see a warning dialog if they navigate away from an <i>In Progress</i> form without first submitting the data to ensure that data is submitted. When prompted with the warning dialog, users can choose to submit the form, continue editing the form, or leave the page.	Clinical Research Coordinator, Investigator, Sub Investigator
Site Users	ILB Lab Forms Marked as "Lab Test Not Performed"	EDC		Sites		Labs	Medium	Users can no longer mark a Lab Form as Intentionally Left Blank. Instead, they can mark blank Lab forms as Lab Tests Not Performed.	Investigator, Sub Investigator, Clinical Research Coordinator
Site Users	Study Closeout: Include Restricted Data	EDC		Sites			High	With this feature, Vault will check if a site contains any restricted forms when generating Closeout PDFs. The Closeout PDF won't be marked as restricted if no restricted data is detected. Site users won't be required to have the restricted data permission in order to download and accept the files.	Investigator, Sub Investigator
Clinical Team, Site Users	Audit Trail Messaging Enhancement for Derived Items	EDC		All		Cross-Form Derivation Version	High	With this release, system- generated derivation values will display in the audit trail as "derived display value set."	All
Clinical Team, Site Users	Changes to Planned DateTime & Event DateTime No Longer Included in Audit Trail	EDC		CRAs, Data Managers, Sites			Low	The Audit Trail will no longer display changes to the Event Datetime and Planned Datetime as these fields are no longer used in EDC.	Clinical Research Associate, Clinical Research Coordinator, Data Manager

Clinical Team	Medical Assessments Audit Trail Enhancements	EDC	Assessment Editor, Assessment Reader	None	This feature adds the audit trail for medical assessments to the UI and PDFs. Audit trails for assessments and assessment questions will now be accessible from the Medical Assessment UI. Those audit trails, along with the supplemental data audit trails, can be included in the assessment PDF.	Editor, Assessment
Clinical Team	Query Teams Support for Multi- Role Security	EDC	CRAs, Data Managers, Lead Data Managers	Query Teams and Multi-Role Security must be enabled	roles after they select a team and save the query.	Clinical Research Associate, Data Manager, Lead Data Manager

Clinical Team	Study Progress Listings Enhancements	EDC	CRAs, Data Managers		Users can schedule up to one daily listing job to send to reports, unless the study is set as a priority study. Users can schedule two additional daily jobs for priority studies. When the study's priority expires, Vault will also automatically expire the additional jobs. We've also added various columns to the following listing jobs. Query Detail Listing changes: New column for Form Status New column for number of query messages Event Progress Listing changes: New columns for Event Date frozen and locked Subject Progress Listing changes: New columns for SDV Completion Date and DMR Completion Date Form Progress Listing changes: New columns for Intentionally Left Blank and ILB Reason	Manager, Lead Data Manager
	Additional Requirements for Cross-Form Derivations	EDC			With this release, we introduced new BRDs for the Cross-Form Derivations feature. There weren't any functional changes. These new requirements were only added to provide additional detail in the BRD.	N/A

Automatic Removal of Stu Access upon Inactivation	All		Super Users, User Administrators		Medium	Vault now automatically removes a user's study access, by clearing the Grant Access checkbox, when they have been inactivated, and it disables the ability to edit an inactive user's details.	Super User, User Administrator
Coder Tools Navigation Refresh	Coder		Coder Administrators		Low	The main navigation in Coder Tools will be moved to the left panel. In addition, the Study Settings tab allows Coder Admins to filter for active Studies.	Clinical Coder Administrator
Data Added via API has a Read only Option	_	No - Future Release	API Read Write	API	Low	When an Event Date or Item value is set via the API and marked as Externally Owned, EDC marks that Event Date or Item as read-only and prevents changes. In 23.1 APIs, Externally Owned is set to true by default. Organizations can choose to move their active integrations forward to use this feature. Otherwise, they can stay on earlier API versions.	API Read Write, Clinical Research Coordinator, Investigator, Sub Investigator
Deploy from Development to Validation Environments	EDC		Deployment Administrators, Super Users		High	Users can now deploy their Study from a Development environment into a Validation environment.	Deployment Administrator, Super User
Disable Manua Casebook Creation	EDC		Lead Data Managers, Librarians, Study Designers, Vault Administrators	EDC Tools	Low	This feature added a new setting to EDC Tools > Settings, "Disable Manual Casebook Creation". When this is set to <i>Yes</i> , Vault disables the "+ New Casebook" button in the Data Entry tab.	
Display Permission Dependencies Role Management U			Lead Data Managers, User Administrators, Super Users		Low	This feature provides a tooltip (hover-over help) in the editable Role Management grid when permissions are dependent on an already selected permission. When users hover over the checkmark, it shows a list of dependencies.	Lead Data Manager, User Administrator, Super User

E2BLink: Configure St Values in E2 XML		Safety Administrators Study Designe	•	L	.ow	Safety administrators can now configure the values sent for the following static fields in the E2B XML: Subject ID E2B Location (D.1), Subject ID Format in E2B, Sender Type E2B Value (C.3.1), Primary Source Qualification E2B Value (C.2.r.4), and Study Drug Classify when ConMed Suspect (G.k.1).	Safety Administrator, Study Designer
E2BLink: Du Inclusion Cri for Related F	eria	Study Designe Safety Administrators		N	<i>l</i> ledium	Safety administrators can now send related data with a Safety Case automatically via configurable duration criteria rules. Prior to this release, it was only possible to include related data that was linked by site.	Study Designer, Safety Administrator
E2BLink: SA Not Submitte Email Alerts		Safety Administrators Study Designe		N	<i>f</i> ledium	When a site user enters data for a serious adverse event, but doesn't submit the form, a safety administrator can configure vault to send a notification to both the site user and selected study personnel about the incomplete form. Users can manage alert recipient from the new Safety Integrations area of System Tools.	Safety Administrator, Study Designer
Enablement Change: Stu Data Extract Compression	SAS	Lead Data Managers		N	N/A	This feature turns on the "Enable SAS Artifact Compression" feature for all vaults, which compresses the SAS zip file. SDE Versions 22R1 and later will automatically have SAS compression enabled. Previous SDE versions will be affected.	Lead Data Manager
Labs: Modifice Support for Number Date Type	(Labs)	Yes Lab Data Managers, Stu Designers	Labs	Data Model 2, Global Labs	<i>l</i> ledium	Vault now supports lab modifier results using the number data type.	Data Manager, Lab Data Manager, Lead Data Manager, Study Designer

Labs: Support Multiple Languages	for EDC, EDC (Labs)	Data Managers, Lab Data Managers, Lead Data Managers, Study Designers, Super Users	Labs	Labs	Medium	This feature allows users to upload translated values for codelists, units, and analytes.	Data Manager, Lab Data Manager, Lead Data Manager, Study Designer
Permission Grouping in Ro Management	All	Lead Data Managers, User Administrators, Super Users			Low	The Role Management page now has roles grouped into expandable sections: Standard Tabs, Data Entry, Queries, Review, Assessments, Study Administration, Coder, Study Design, Library, Protocol Deviations, Labs, Randomization, Site Closeout, CDB, User Defined Objects, and User Defined Permission Sets.	Lead Data Manager, User Administrator, Super User
Prevent Post- Deployment Removal of Ro from Deployments		Deployment Administrators, Super Users, User Administrators			Medium	Users can no longer remove custom roles from the deployment list, if a deployment has already occurred. This prevents the unintentional removal of roles.	Deployment Administrator, Super User, User Administrator
Reconcile Miss References During Study Data Copy	sing EDC	Deployment Administrators			N/A	Vault now reconciles missing references when copying data from production to a post-production test (PPT) environment.	Deployment Administrator
Removed Acti Menu from LM External Connections		Super Users, Vault Administrators			Low	With this release, we removed the extraneous Actions menu icon from System Tools > External Connections > LMS External Connections.	Super User, Vault Administrator
Removed Leg- PDF V1 Featu		Vault Administrators			N/A	With this release, we removed the PDF V1 feature, as this feature is no longer in use by any customers.	Vault Administrator

Review Plan Assignment UI Enhancements	EDC	Lead Data Managers, Librarians, Study Designers, Super Users	Review Plan Assignment V2 or V3	Low	introduced two new tabs to EDC Tools, Review Plan Assignment Criteria and	Lead Data Manager, Librarian, Study Designer, Super User
Rules Archive	EDC	Librarians, Study Designers		Medium	When deleting rules, Vault now marks those deleted rules as Archived. After a user executes the Delete action against a Rule, Vault applies the Archived status, marks the rule as Inactive, and hides the rule from the User Defined Rules listing. Users can then view and restore these archived rules. Archived rules behave in the same was as Inactive rules. Vault excludes these rules from validations and documentation, deploys them (in the Archived status), and prevents users from marking them as Active. That prevents these rules from executing.	Designer

Su Da	ules: Remove ubject Status ate on Status ollback	EDC	Librarians, Study Designers, Super Users	Studio		Medium	With this release, when data changes for a subject, if a Set Subject Status rule that previously evaluated as true is now false, Vault can clear the status date at that time. This is controlled by the new setting in Studio > Settings, Enable Subject Status Date Rollback.	Librarian, Study Designer, Super User
Ev Sc @	ules: Sort vents by chedule for PreviousEvent ules	EDC	Librarians, Study Designers	Studio	Expression Engine V2	Medium	With this release, Studio users can select Schedule for Sort Events By for rules using @PreviousEvent. This sorts Events in the order the schedule is designed in Studio, instead of by Event Date. When Schedule is selected, users can now also clear the Skip Intentionally Left Blank and Did Not Occur values checkbox.	Librarian, Study Designer
De	DE: Add Object efinition Names Extracts	EDC	Lead Data Managers			Low	In the 23R1 version of the SDE, various clinical and system datasets will include the following object definition names as new columns: Event Group Definition Name, Event Definition Name, Form Definition Name, Item Group Definition Name, and Item Definition Name.	Lead Data Manager

SDE: General	EDC	Lead Data	Low	The following enhancements Lead Data
Enhancements		Managers		have been made to the 23R1 Manager version of the SDE:
				Users will have the option to select a boolean formatting
				type which will determine how booleans are displayed in both
				clinical and system datasets. This formatting doesn't apply to
				the definitions files
				If there are duplicate column headers, both the CSV and
				SAS files will follow a
				deduplication pattern of appending _2, _3, etc. to each
				additional repeating column. When running the "SAS with
				CSV and XPT", Export File
				Type option, users will see an additional column for "SAS
				Column" in the Study
				Definitions file so that they can compare the column headers
				between CSV and SAS for any differences (such as SAS
				column header truncation for
				column headers greater than 32 characters in length)
				The SYS_Q dataset will have a new column for the
				LASTCLOSEDDT (Query Last
				Close Date)
				• The rows in the casebook_schedule.csv,
				casebook_definition_summary. csv, event_definitions,
				form_definitions, and
				item_defintions files in the definitions folder will be
				ordered according to the studio study Schedule Design within
				each casebook version

SDE: Lab Forms	EDC, EDC	Lead Data	Low	In the 23R1 version of the	Lead Data
Now Use	(Labs)	Managers		SDE, clinical forms configured	Manager
Compact/Long				with Local Labs will be	
Format				formatted to decrease the	
				number of columns outputted	
				so that the dynamically-	
				generated Labs columns will	
				be shared across all Lab	
				Analytes on the form instead of	:
				having multiple columns per	
				analyte.	

SDS Usability Improvements	EDC	Librarians, Study Designers, Super	Low	This release includes the following SDS enhancements: Librarian, Study Designer, Super
improvements		Users		Added columns for missing properties and system edit checks to the Schedule Tree tab and updated column headers and order of columns for consistency
				Added missing columns to the Form Definitions tab, relabeled column headers to match UI, and removed obsolete/retired columns
				Added Last Modified columns to Form Definitions and Schedule Tree
				The "Include Rules" option is now checked by default when generating an SDS from Studio
				Updated formatting of the Review Plan tab including newly-formatted rows for different object types to match the Form Definition tab and carried down column values for filtering
				Removed obsolete columns and added a <i>Form Label</i> column in the Rules tab
				Added Form Name and column headers to Schedule Grid tab
				Updated the Summary tab for clarity
				Added and updated columns on the Codelists and Unit Codelists tabs
				Added <i>Object Name</i> columns to the Date Comparisons tab

Setting Activation Date via User Import	EDC	Super Users, User Administrators	Low	This feature allows user administrators to make changes to a user's Activation Date creating users via import from file. In addition, if an Activation Date is not specified, Vault uses the current date and indicates that in a warning during import preview.	
Studio Usability Improvements	EDC	Librarians, Study Designers	Med	This release includes several usability improvements for Studio: • Schedule is now the default landing page when opening Studio. • The Comparison Report (diff report) no longer reflects changes to the rule action order that are controlled by the system. • We made some minor formatting, processing, and logging changes to export and import for study languages. • We relabeled the Future Date property as No Future Date to clarify the purpose of this property. • The default value for Repeat Maximum on Event Groups is now "50" instead of "9999". • Studio users can edit library settings and some study settings after a Study is deployed. • If no Form Links are included in the study's schedule, Studio doesn't run validations against Form Links. • We added validation errors for unsupported uses of crossform derivations.	

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Study Role Enhancements	AII	Lead Data Managers, Super Users, User Administrators, Vault Administrators	High	With this release, we made the following changes to permissions and standard Study Roles: • Added the CDB Tools permission and assigned it to the CDMS Data Manager and CDMS Lead Data Manager roles • Added the Configure CDB permission and assigned it to the CDMS Super User role. This also removed the Configure Queries permission. • Added the Manage Review Plan Assignment Criteria and Manage Review Plan Manual Assignment permissions • Assigned the Manage Jobs permission to the CDMS Clinical Research Associate and CMDS Data Manager roles • Assigned the View Users permission to the CDMS API Read Only and CDMS API Read Only and CDMS API Read Write roles • Added the Safety Integrations Tab permission and assigned it to the CDMS Lead Data Manager, CDMS Data Manager, CDMS Data Manager, CDMS Study Designer, CDMS Study Designer, Read Only, CDMS
				permission to the CDMS API Read Write role • Added the Safety Integrations Tab permission and assigned it to the CDMS Lead Data Manager, CDMS Data Manager, CDMS Safety Administrator, CDMS Study
				Write, and CDMS User Administrator roles • Added the View Safety Integrations permission and assigned it to the CDMS Lead Data Manager, CDMS Data Manager, CDMS Safety Administrator, CDMS Study Designer, CDMS Study Designer Read Only, CDMS Super User, and CDMS User

Administrator roles

Support for Custom Vault Tab Collections	All	l I	Vault Administrators		N/A	CDMS now supports the Tab Collections feature for custom Vault tabs from the Vault Platform.	Vault Administrator
Sync Synonym Lists	EDC	l I	Coder Administrators	Vault Admin	Medium	Users can designate one synonym list to perform all autocoding and suggestions for two vaults. Autocoding and Suggestions will be consistent across all Studies that span two vaults.	Clinical Coder Administrator
UI for Orphaned & Deleted Coder Items	Coder		Study Designers	Studio	Medium	Study Designers can still see coding configurations for Form and Item Definitions from an orphaned Verbatim Item Definition or an orphaned or deleted related coding Item Definition. Study Designers can then select a new Item Definition or make the mapping not required (in the case of Related Coding Item Definitions only). Users can also delete the Coding Configuration on the Form Definition entirely.	
User Access Report	All		Super Users, User Administrators		High	This release introduces the User Access Report, which tracks changes to a user's access at the study and vault levels. User administrators can download this report (CSV), covering up to six months, from Tools > System Tools > Users. We removed columns and the tracking of events related to user access changes from the User Activity Report, as these are now covered by the User Access Report.	Super User, User Administrator

Veeva CDB Features								
Day 1 Impact to Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
	CDB Export Audit Log Enhancements	CDB	Data Managers, Lead Data Managers			High	CDB now captures changes to export package blinding and unblinding in the Export Audit Logs.	Data Manager, Lead Data Manager
	CDB Navigation Enhancements	CDB	Data Managers, Lead Data Managers			Low	This release includes the following enhancements to navigation in CDB: • Users can search for a <i>Study</i> from the Studies page. • CDB shows a Last Listing Visited link on the Studies page. • Users can search for a listing from any page in the application, via the new search option in the top navigation bar. • CDB allows users to open a listing in a new browser tab.	Data Manager, Lead Data Manager
	Clean Patient Tracker	CDB	Data Managers, Lead Data Managers			High	managers to review the cleanliness of	Data Manager, Lead Data Manager
	Clone from Study	CDB	Super Users	CDB		High	CDB users can select listings, checks, and views from a defined source study and clone them into their current study. CDB provides a validation summary for each listing, check, or view indicating whether that it is compatible or incompatible with the target study design. Users can then review the validation summary, make necessary changes and import the desired cloned objects. After import, cloned objects can be reviewed, modified, and deployed to production.	Manager, Super User

Configure Core Data Listings	CDB	Super Users	CDB		Administrators can configure which header columns to include and which formats to use for <i>Core Listings</i> from the new Configurations area. These configurations apply to all <i>Studies</i> and all of their Core Listings in the vault. Configurations have a review and approval workflow. The following configurations are available: • Header Columns • Date, DateTime, and Time Formats • Included UOM Fields • Included Codes, Decodes	Data Manager, Lead Data Manager, Super User
Create & Manage Favorites		Data Managers, Lead Data Managers			With this release, CDB users can mark listings, checks, and views as Favorites. They can manage their favorites from the Favorites panel, which is accessible via the Favorites button in the top navigation menu.	Data Manager, Lead Data Manager
Fill CQL Function	CDB	Data Managers, Lead Data Managers		N/A	CQL now supports the Fill function.	Data Manager, Lead Data Manager
Third Party External ID Support	CDB	Data Managers, Lead Data Managers			When importing third party data, CDB allows users to specify a Row External ID used to uniquely identify a row of data that a query is associated with. Users can see the Row External ID attribute in the core Query Listings, as well as in the CQL @QRY dataset.	Data Manager, Lead Data Manager

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 3/3/2023

Date	Description	Impact
2/27/2023	Published the initial version of the RIA	N/A
3/10/2023	Added the "Fill CQL Function" and "Reconcile Missing References During Study Data Copy" features Updated "Users with Day 1 Visibility" for "Create & Manage Favorites" Removed "Audit Event for Item Change Reason on Create" from the CDMS RIA (this feature is included in the Migration Vault RIA) Updated the description for "Automatic Removal of Study Access upon Inactivation", "Display Permission Dependencies in Role Management UI", "User Access Report", "Study Role Enhancements", and "Review Plan Assignment UI Enhancements"	The RIA includes an up to date list of features.
3/16/2023	Updated the description for "SDE: General Enhancements", "Study Progress Listings Enhancements", and "Review Plan Assignment UI Enhancements"	The RIA includes up to date feature descriptions.
4/14/2023	Updated the description for "SDE General Enhancements", "Study Progress Listing Enhancements", "Study Role Enhancements", and "Studio Usability Enhancements"	The RIA now has up to date feature descriptions.
4/21/2023	Updated the description for "Study Role Enhancements"	The RIA now includes up to date feature descriptions.